7. Discounting of Surgical Procedures

To be consistent with Medicare policy and regulations governing payment for ambulatory surgical services furnished in a physician’s office and in an ASC, we proposed under the hospital outpatient PPS to discount payment amounts when more than one procedure is performed during a single operative session or when a surgical procedure is terminated prior to completion. Specifically, we proposed that when more than one surgical procedure with payment status indicator "T" is performed during a single operative session, we would pay the full Medicare payment and the beneficiary would pay the coinsurance for the procedure having the highest payment rate. Fifty percent of the usual Medicare PPS payment amount and beneficiary coinsurance amount would be paid for all other procedures performed during the same operative session to reflect the savings associated with having to prepare the patient only once and the incremental costs associated with anesthesia, operating and recovery room use, and other services required for the second and subsequent procedures.

We also proposed to require hospitals to use modifiers on bills to indicate procedures that are terminated before

completion. Modifier -73 (Discontinued Outpatient Procedure Prior to Anesthesia Administration) would identify a procedure that is terminated after the patient has been prepared for surgery, including sedation when provided, and taken to the room where the procedure is to be performed, but before anesthesia is induced (for example, local, regional block(s), or general anesthesia). Modifier-52 (Reduced Services) would be used to indicate a procedure that did not require anesthesia, but was terminated after the patient has been prepared for the procedure, including sedation when provided and taken to the room where the procedure is to be performed. We proposed to pay 50 percent of the usual Medicare PPS payment amount and beneficiary coinsurance amount for a procedure terminated before anesthesia is induced. Modifier -74 (Discontinued Procedure) would be used to indicate that a surgical procedure was started but discontinued after the induction of anesthesia (for example, local, regional block, or general anesthesia), or after the procedure was started (incision made, intubation begun, scope inserted) due to extenuating circumstances or circumstances that threatened the well-being of the patient. To recognize the costs

incurred by the hospital to prepare the patient for surgery and the resources expended in the operating room and recovery room, the hospital will receive full payment for a procedure that was started but discontinued after the induction of anesthesia or after the procedure was started, as indicated by a modifier -74. The elective cancellation of procedures would not be reported. If multiple procedures were planned, only the procedure actually initiated would be billed.

Comment: Some commenters asked us to clarify how the policy would be applied. For example, one commenter asked whether the surgical discounting methodology would apply in the following situation: contrast x-ray of lower spine (CPT code 72265) is followed by contrast CAT of the spine (CPT code 72132). Both procedures have related surgical codes (CPT codes 62270 and 62284). Other commenters provided examples that were similar in nature but involved other codes.

Response: We proposed to apply the reduced payment for multiple procedures to surgical procedures only, that is, those CPT codes that have a payment status indicator "T." Therefore, services such as CPT codes 72265 and 72132 that

have a payment status indicator of "S" would not be subject to the multiple procedure discount, whereas CPT codes 62270 and 62284, which are surgical procedures and have a payment status indicator of "T," would be subject to the multiple procedure discount. Hypothetically, if all four codes were provided in a single operative session, as suggested by this commenter, then the reduced payment would apply only to the surgical procedure with the lower payment rate. (For the record, we have responded to the commenter's example in order to clarify how the multiple procedure discount would apply in a hypothetical situation. However, we question whether the suggested combination of codes would be covered if actually performed during the course of a single patient encounter.)

Comment: Commenters asked what factors guided our assignment of payment status indicator "T" to a code.

Response: We generally assigned the payment status indicator "T" to surgical services. Our medical advisors and staff will continue to review the designation of status indicators and we may propose revisions in the future.

Comment: A variety of commenters stated that the reduced payments for multiple procedures would

inappropriately reduce payments for a second procedure. Some were concerned that application of the multiple procedure discount could result in hospitals being less likely to offer procedures assigned the payment status indicator "T." These commenters recommended that we change all "T" payment indicators to a different indicator such as "S," which we define as a significant procedure not reduced when multiple, until we have had an opportunity to collect reliable cost data upon which to base payment decisions about discounting.

Response: We continue to believe that the proposed reduced payment for multiple surgical procedures is reasonable. We disagree that hospitals would be less likely to provide these services. We believe there clearly are savings achieved when more than one surgical procedure is performed during a single operative session. The patient has to be prepared for surgery only once, and the costs associated with anesthesia, operating and recovery room use, and other services required for the second procedure are incremental.

Comment: Some commenters questioned whether the reduced payment for multiple procedures applied to the

beneficiary coinsurance as well as to the Medicare program payment. Others did not understand how this reduced payment was accounted for in determining the conversion factor.

Response: The reduced payment for multiple procedures would apply to both the beneficiary coinsurance and the Medicare payment. In order to do this in a "budget neutral" manner, we increased the conversion factor to account for the reduced payments for multiple procedures. In this way, total payments in the aggregate are not affected.

Comment: One commenter believes we should exclude from the multiple-procedure discount those procedures that were subject to a 50 percent reduction under the previous cost-based system because those procedures were recognized as being an adjunct to a primary procedure. The commenter believes that we had already factored these discounts into our cost determinations and would therefore be inappropriately reducing payment even further for these procedures.

Response: We disagree with the commenter. In determining the weights for the APC groups, we included only single procedure claims. Multiple procedure reductions existing under the previous cost-based system would not have

been reflected in these single procedure claims, and, therefore, do not affect the APC payment weights.

Final Action

Under the hospital outpatient PPS, we will discount payment amounts for surgical procedures when more than one procedure is performed during a single operative session or when a surgical procedure is terminated prior to completion. Parallel discounts will apply to beneficiary coinsurance amounts.

8. Payment for New Technology Services

a. Background

We proposed to price a new item or service that was assigned a new HCPCS code by classifying the new code to whichever existing APC group most closely resembled the item or service in terms of its clinical characteristics and estimated resource use. We proposed to use the group weight, payment rate, and coinsurance amount established for the existing APC to price the new code for at least 2 years to give us an opportunity to collect cost data for the new item or service.

After we published our proposed rule, the Congress expressed concern in the conference report accompanying the

BBRA 1999, that our proposed PPS does not adequately address "issues pertaining to the treatment of . . . new technology." (See H. R. Rep. No. 436 (Part I), 106th Cong., 1st Sess. 868 (1999).) Therefore, the Congress enacted "transitional pass-throughs" in section 201(b) of the BBRA 1999 that provide an additional payment for "new medical devices, drugs, and biologicals" that do not otherwise meet the definition of current orphan drugs, or current cancer therapy drugs and biologicals and brachytherapy, or current radiopharmaceutical drugs and biological products. (See section III.D of this preamble for a discussion of how we are implementing the transitional pass-throughs.)

b. Comments and Responses

Comment: The most frequent commenters regarding our treatment of new technology under the proposed hospital outpatient PPS were device manufacturers and pharmaceutical companies and their trade associations. Commenters were concerned because the proposed APC payment rates were developed using 1996 cost data that do not reflect the cost of many new technologies introduced subsequent to 1996. Commenters believe that the proposed method of ratesetting under the APC system lacks the flexibility needed to

recognize emergent technologies in a timely manner. In the view of the commenters, assigning new technologies to existing APC groups pending the collection of cost data would result in underpayment, thereby discouraging the adoption of new technologies.

Commenters further stated that the proposed payment rates for current yet relatively new devices were too low and would favor continued use of older, less effective regimens on the basis of financial pressures rather than on the improved clinical outcomes of newer technology. Some commenters, concerned that we will not update codes or payment rates quickly enough to allow hospitals to pay for new technologies, recommended that we assign HCPCS codes as soon as products become available and alter APC group weights to account for a new technology. These commenters believe that the time lapse between coding updates is a barrier to innovation because it can take several years for a code to be issued for a new surgical technique, and until a new code is issued, facilities must bill for new surgical techniques as "unlisted procedures" resulting in the lowest payment rate for the category of surgery.

One commenter urged that we implement a payment carve-out for certain drug and biological therapies and pay for these items on a reasonable cost basis in order to provide timely patient access to many new pharmaceutical and biotechnology products. The same commenter recommended that if we reject a complete carve-out, then, at a minimum, we should pay for new products introduced after 1996 on a reasonable cost basis for 1 year to adequately compensate companies for developing new and more effective products. Another commenter recommended that we increase the number of APC groups to better reflect services with similar cost structures.

One professional association recommended abandoning the APC group system altogether and pricing services individually because assigning new technology and most costly procedures to APC groups with established lower cost procedures creates a strong disincentive for hospitals to provide new or improved items or services and, in the case of newer, higher cost drugs, encourages hospitals to develop formularies and practice patterns based on financial considerations rather than on the medical value of drugs.

Technologies that commenters cited as being inadequately addressed by the proposed outpatient PPS include new technologies based on molecular genetics; gamma knife procedures used in radiation surgery; and prostatic microwave thermotherapy (transurethral microwave thermotherapy (TUMT)) which a commenter said has a direct cost of $1,918 and, factoring in indirect costs, a total cost of $2,623.

Response: The concerns expressed by commenters regarding new technology items and services highlight two issues. The first is specific to the data used to construct APC groups and calculate their prices at the start of the PPS. As required by section 1833(t)(2)(C) of the Act, we are using claims data from 1996 as the basis for determining APC group weights and payment rates under the new system. The 1996 data do not capture items and services that have emerged since that time and that are now in use. The second issue relates to new items and services that will be introduced in the future, after the outpatient PPS is implemented. Postponing the adjustment of APC groups and weights for several years to allow for the collection of

cost data would potentially inhibit the dissemination of medically desirable innovations.

We recognize the concerns raised by commenters about our proposed treatment of new codes under the hospital outpatient PPS. We therefore have developed a process that we believe will allow us to recognize new technologies on an ongoing basis as expeditiously as our systems permit. We expect that this process, which we explain below, combined with the transitional pass-throughs established by section 201(b) of the BBRA 1999 (which we describe in section III.D of this preamble), will provide additional payment for a significant share of new technologies.

In this final rule, we have created special APC groups to accommodate payment for new technology services. In contrast to the other APC groups, the new technology APC groups do not take into account clinical aspects of the services they are to contain, but only their costs. We will assign new items and services that we determine cannot appropriately be placed in existing APC groups for established procedures and services to the new technology APC groups.

The new technology APC groups, which are now largely unpopulated, are already defined in our claims processing system for the outpatient PPS, and we have established payment rates for the APC groups based on the midpoint of ranges of possible costs, for example, the payment amount for a new technology APC group reflecting a range of costs from $300 to $500 would be set at $400. The cost range for the groups reflects current cost distributions, and we reserve the right to modify the ranges as we gain experience under the outpatient PPS. The final APC groups for new technology are groups 0970 through 0984 and cover a range of costs from less than $50 to $6,000. Upon implementation of the outpatient PPS, we will make payment for the following new technology services under the new technology APCs:

53850 Transurethral destruction of prostate tissue; by microwave thermotherapy

53852 Transurethral destruction of prostate tissue; by radiofrequency thermotherapy

96570 Photodynamic therapy, first 30 minutes

96751 Photodynamic therapy, each additional 15 minutes

G0125 PET lung imaging of solitary pulmonary nodules, using 2-(Fluorine-18)-Fluoro-2-Deoxy-D-Glucose (FDG), following CT (71250/71260 or 71270)

G0126 PET lung imaging of solitary pulmonary nodules, using 2-(Fluorine-18)-Fluoro-2-Deoxy-D-Glucose (FDG), following CT (71250/71260 or 71270); initial staging of pathologically diagnosed non-small cell lung cancer

G0163 Positron emission tomography (PET), whole body, for recurrence of colorectal metastatic cancer

G0164 Positron emission tomography (PET), whole body, for staging and characterization of lymphoma

G0165 Positron emission tomography (PET), whole body, for recurrence of melanoma or melanoma metastatic cancer

G0166 External counterpulsation, per treatment session

G0168 Wound closure by adhesive

The new technology APC groups give us a mechanism for initiating payment at an appropriate level within a relatively short timeframe, and certainly less than the 2 or 3 years that we contemplated in our proposed rule. As in the case of items qualifying for the transitional pass-through payment, placement in a new technology APC will be temporary. After we gain information about actual hospital

costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs. If we cannot move the new technology service to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, we will create a separate APC for such service. We will retain a service within a new technology APC group for at least 2 years, but no more than 3 years, consistent with the time duration allowed for the transitional pass-through payments. Movement from a new technology APC to a clinically-related APC would occur as part of the annual update of APC groups. Beneficiary coinsurance amounts for items and services in the new technology APC groups are 20 percent of the payment rate set for the new technology APCs.

We ask that interested parties take the following steps to bring to our attention services that they believe merit consideration for pricing using the new technology APC groups. Mail requests for consideration of possible new technology services that have established HCPCS codes to the following address ONLY: PPS New Tech/Pass-Throughs, Division of Practitioner and Ambulatory Care, Mailstop C4-03-06, Health Care Financing Administration, 7500 Security Boulevard, Baltimore, MD 21244-1850.

To be considered, requests **MUST** include the following information:

! Trade/brand name of item.

- A detailed description of the clinical application of the item, including HCPCS code(s) to identify the procedure(s) with which the item is used.
- Current cost of the item to hospitals (i.e., actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind). In other words, submit the best and latest information available that provides evidence of the hospital's actual cost for a specific item.
- If the item is a service, itemize the costs required to perform the procedure, e.g., labor, equipment, supplies, overhead, etc.
- If the item requires FDA approval/clearance, submit information that confirms receipt of FDA approval/ clearance and the date obtained.
- If the item already has an assigned HCPCS code, include the code and its descriptor in your submission plus a dated copy of the HCPCS code “recommendation application” previously submitted for this item.
- If the item does not have an assigned HCPCS code, follow the procedure discussed, below, for obtaining HCPCS codes and submit a copy of the application with our payment request.
- Name, address, and telephone number of the party making the request.

! Other information as HCFA may require to evaluate specific requests.

We believe some items not yet known to us do not yet have assigned HCPCS codes. We expect to use national HCPCS codes in the hospital outpatient PPS to the greatest extent possible. These codes are established by a well-ordered process that operates on an annual cycle, starting with submission of information by interested parties due by April 1 and leading to announcement of new codes in October of each year. This process is described, and relevant application forms are available, on the following HCFA website: http://www.hcfa.gov/medicare/hcpcs.htm.

Considering the exigencies of implementing a new system, we intend to establish temporary codes in 2000 to permit implementation of additional payments for other eligible items effective beginning October 1, 2000. The process for submitting information will be the same as for national codes.

For new technology services that DO NOT have established HCPCS codes, submit the regular application for a national HCPCS code in accordance with the instructions found on the internet at http://www.hcfa.gov/medicare/hcpcs.htm. Send applications for national HCPCS codes to: C. Kaye Riley, HCPCS

Coordinator, Health Care Financing Administration, Mailstop C5-08-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. A fuller discussion of the HCPCS process and schedule is in section III.D.6 of this preamble.

Because of staffing and resource limitations, we cannot accept requests by facsimile (FAX) transmission.

Because of claims processing systems constraints, a new technology payment rate can only be initiated at the start of a calendar quarter. Since we will update our outpatient PPS quarterly to include new technology additional services, October 1, 2000 is the earliest date that we will implement payment for additional new technology services other than for those items beginning on July 1, 2000. In general, we expect to be able to complete action on requests to assign an item or service to a new technology APC group in about 6 months from the date we receive the request.

In order to be considered for assignment to a new technology APC group, an item or service must meet the following criteria:

! The item or service is one that could not have been billed to the Medicare program in 1996 or, if it was available in 1996, the costs of the item or service could not have been adequately represented in 1996 data.

! The item or service does not qualify for an additional payment under the transitional pass-through provided for by section 1833(t)(6) of the Act, as amended by section 201(b)

of the BBRA 1999, and 42 CFR 419.43(e) as a current orphan drug, as a current cancer therapy drug or biological or brachytherapy, as a current radiopharmaceutical drug or biological product, or as a new medical device, drug, or biological.

! The item or service has a HCPCS code. (See section III.D for additional information about obtaining HCPCS codes.)

! The item or service falls within the scope of Medicare benefits under section 1832(a) of the Act.

! The item or service has been determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act.

Final Action

We are initiating a method to pay for new technology services that are not addressed by the transitional pass-through provisions of the BBRA 1999.